

REMARKS

Claims 1-47 are pending, with claims 4, 5, 10, 12, 14, 22, 24, 26, 33, 34, 37, 38, 44 and 46 having been withdrawn pursuant to an election of species requirement. Claims 45 and 47 are amended. Reexamination and reconsideration of the pending claims, as amended, are respectfully requested.

Claims 1-3, 6, 7, 13, 15, 18, 20, 25, 27, 28, 31, 39, 42 and 45 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,073,048, issued to Kieval et al. (hereinafter "Kieval"), in view of U.S. Patent No. 3,522,811, issued to Schwartz et al. (hereinafter "Schwartz"). Applicants respectfully traverse this rejection.

Independent claims 1 and 20 of the present application are each directed to "A method of disposing an activation device *on a carotid sinus* of a patient..." [emphasis added]. Claim 1 includes "...positioning the device proximate the carotid sinus such that the base extends around at least a substantial portion of the circumference of the carotid sinus and the electrodes extend around the carotid sinus less than the base." Claim 20 includes "positioning the device proximate the carotid sinus such that the electrodes are spaced about at least a portion of the circumference of the carotid sinus."

Independent claim 31 of the present application is directed to "A device for mounting *on a carotid sinus* of a patient to induce a baroreflex..." including "a base having a length sufficient to extend around at least a substantial portion of the circumference of the carotid sinus." [emphasis added] Independent claim 45 is directed to "A device for activating a baroreflex in a carotid sinus of a patient..." including an "electrode assembly adapted to be placed *on the carotid sinus* such that the length of the electrodes runs generally parallel to a longitudinal axis of the carotid sinus." [emphasis added]

In contrast to claims 1, 20, 31 and 45 of the present application, all of which include a device for placement *on a carotid sinus*, Kieval is directed to devices and methods for

direct attachment to, and stimulation of, the carotid sinus nerves. The Kieval carotid sinus nerve electrodes 160c and 160d are placed directly on, and used to stimulate, carotid sinus nerves 155 and 156. (See Figure 7 and column 6, lines 8-10). Kieval does not teach, describe or suggest placement of a device on a carotid sinus, as opposed to a carotid sinus nerve. The carotid sinus is a pocket or deviation in the carotid artery at the bifurcation of its internal and external branches in the neck where baroreceptors and chemoreceptors are found. The carotid sinus nerve is a nerve located adjacent to the carotid sinus. Positioning an activating device on a carotid sinus is advantageous for allowing activation of baroreflex structures other than or in addition to carotid sinus nerves, such as baroreceptors.

Schwartz is similarly limited to devices directly attached to carotid sinus nerves. For example, Schwartz states, "The present structure is designed to transmit an electrical impulse specifically and solely to a surgically exposed carotid sinus nerve." (Column 2, lines 25-27.) As shown in Figures 1 and 2, the Schwartz device has a flap 14 and a tab 15 that lie over electrodes 6 and 7, and that wrap around a surgically exposed carotid sinus nerve 12 and are then sewn together by surgical stitching 16. Schwartz does not teach, describe or suggest placement of a device on a carotid sinus, as opposed to a carotid sinus nerve.

Additionally, neither Kieval nor Schwartz describes a method in which a device is positioned "such that the base extends around at least a substantial portion of the circumference of the carotid sinus," as in claim 1, or "such that the electrodes are spaced about at least a portion of the circumference of the carotid sinus," as in claim 20. Regarding the device claims, neither Kieval nor Schwartz describes a device including "a base having a length sufficient to extend around at least a substantial portion of the circumference of the carotid sinus," as in claim 31. Although Schwartz does describe wrapping a device around a structure, that structure is a surgically exposed carotid sinus nerve, not a carotid sinus.

Therefore, even if Kieval and Schwartz were combined as suggested in the Office Action, the methods and devices of independent claims 1, 20, 31 and 45, as well as the claims that depend from them, would not be achieved.

Claims 8, 9, 16, 17, 21, 23, 29, 30, 32, 35, 36, 40 and 41 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over a "modified Kieval," in view of Schwartz, and further in view of U.S. Patent No. 5,938,596 issued to Woloszkò et al. (hereinafter "Woloszko"). Applicants respectfully traverse this rejection.

First, Applicants do not understand the meaning of "modified Kieval" as referenced on page 4, first paragraph of section 5, of the Office Action. Applicants do not know what modifications are being referred to and contend that there is no motivation or teaching to modify Kieval in a way that would lead to the devices or methods of the above-listed claims.

Second, each of the above-listed claims depends from either claim 1, claim 20 or claim 31. For all the reasons stated above, even if Kieval and Schwartz were combined, neither the methods of claims 1 and 20 nor the device of claim 31 would be achieved. Woloszko is directed to "a nerve electrode" for direct attachment to a nerve, and is "particularly designed for stimulation of the nerves of the sacral root." (Column 2, lines 44-45.) Woloszko does not teach, describe or suggest attachment to a carotid sinus, as in independent claims 1, 20 and 31 and the above-listed dependent claims of the present application.

Therefore, even if Kieval, Shwartz and Woloszko were combined as suggested in the Office Action, the methods and devices of claims 8, 9, 16, 17, 21, 23, 29, 30, 32, 35, 36, 40 and 41 would not be achieved.

Claims 19, 43 and 47 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over "modified Kieval ('048)," in view of Schwartz, and further in view of U.S. Patent No. 6,178,349 issued to Kieval (hereinafter "Kieval '349"). Applicants respectfully traverse this rejection.

Again, Applicants do not understand the reference to "modified Kieval ('048)."
Additionally, claims 19 and 43 each include a base that has "sufficient structural integrity to grasp the *carotid sinus*" [emphasis added]. Kieval, Schwartz and Kieval '349, by contrast, describe devices for attachment to a carotid sinus *nerve*. As noted by the Examiner, the device in Kieval '349 includes a base "having sufficient structural integrity to grasp the *nerve* for sustaining long-term contact between the *nerve* and the electrode." Claims 19 and 43, by contrast, grasp the carotid sinus, which allows for the possibility of activating baroreflex structures other than or in addition to carotid sinus nerves.

As amended, claim 47 is directed to "A method of disposing an activation device on a carotid sinus vascular wall of a patient, the method comprising the steps of:...suturing the base to the vascular wall." As discussed above, Kieval and Schwartz are limited to devices for attachment to carotid sinus nerves and do not teach or suggest suturing to a carotid sinus vascular wall. Similarly, Kieval '349 describes only attachment of electrodes 92, 94, 240, 242 to carotid sinus nerves 64, 66. No suggestion is made in Kieval '349 to suture a base to a vascular wall.

Therefore, even if Kieval, Schwartz and Kieval '349 were combined as suggested in the Office Action, the method and devices of claims 19, 43 and 47 would not be achieved.

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Reply to Office Action of November 4, 2004

PATENT

CONCLUSION

In view of the above amendments and remarks, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'James M. Heslin', written over a circular stamp or mark.

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